

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/SE 2005/000467

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Cover sheet

International patent classification (IPC)

B01D 15/18 (2006.01)
C07K 1/36 (2006.01)

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Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:

- the international application in the language in which it was filed
 a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
 international search (Rules 12.3(a) and 23.1(b))
 publication of the international application (Rule 12.4(a))
 international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this opinion has been established on the basis of (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*):

- the international application as originally filed/furnished

- the description:

pages _____ as originally filed/furnished
 pages _____ received by this Authority on _____
 pages _____ received by this Authority on _____

- the claims:

pages _____ as originally filed/furnished
 pages _____ as amended (together with any statement) under Article 19
 pages _____ received by this Authority on _____
 pages _____ received by this Authority on _____

- the drawings:

pages _____ as originally filed/furnished
 pages _____ received by this Authority on _____
 pages _____ received by this Authority on _____

- a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

- the description, pages _____
 the claims, Nos. _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to the sequence listing (*specify*): _____

4. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages _____
 the claims, Nos. _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to the sequence listing (*specify*): _____

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Box No. V	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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1. Statement

Novelty (N)	Claims <u>1-4, 8, 10-11</u>
	Claims _____
Inventive step (IS)	Claims <u>1-4, 8, 10-11, 15-28</u>
	Claims _____
Industrial applicability (IA)	Claims _____
	Claims _____

2. Citations and explanations:

Most relevant document cited in the International Search Report:

D1: US 3 869 436 A

D1 relates to the fractionating of plasma proteins by ion-exchange chromatography. The method comprises:

- precipitating the globulins in the plasma with poly(ethylene glycol) (PEG),
- centrifuging out all of the precipitate from the remaining solution,
- dissolving the precipitate in sodium acetate-acetic acid,
- adsorbing the globulins from the dissolved precipitate on a cation-exchanger,
- precipitating the eluate with PEG,
- dissolving the precipitate in phosphate buffer, and
- adsorbing the globulins from the dissolved precipitate on an anion-exchanger.

The method according to claims 1-4, 8 and 10-11 lacks novelty in view of D1.

The features of claims 15-17, regarding the design of the ion-exchange matrix, are known per se. They are considered to be merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill.

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Continuation of: BOX V

in order to solve the problem posed. Therefore, the invention according to claims 15-17 is considered to lack an inventive step.

The invention according to the independent claims 20 and 25 relates to a method for isolating an antibody compound from a liquid, comprising contacting the liquid, in the presence of a non-ionic polyether, with an ion-exchange chromatography matrix.

The method according to claim 20 differs from the subject matter of D1 in that the conductivity is specified to equivalent to 200 mM NaAc. NaAc is mentioned in D1 but the conductivity is not specified. However, this difference is not considered inventive. Thus, claim 20 and the dependent claims 21-24 lack an inventive step.

In independent claim 25, the design of the ion-exchange matrix is specified. For the same reasons as set out above, in connection with claims 15-17, the subject matter of claims 25-27 is considered to lack an inventive step.

Claims 18-19 and 28 relate to kits with separate compartments intended for antibody isolation. Such kits are well-known to a person skilled in the art and this solution has already been applied for the same purpose in similar contexts. Therefore, the subject matter of claims 18-19 and 28 is not considered inventive.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

In claims 7-9, it seems that the words "according to any one of the preceding steps" should be replaced by "according to any one of the preceding claims".